SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
		1 | 66

2. CONTRACT NO.	3. SOLICITATION NO.	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
	W81XWH-11-R-0014	[ ] SEALED BID (IFB) [X] NEGOTIATED (RFP)	23 Jun 2011	W74MYF0175N615

7. ISSUED BY	CODE	8. ADDRESS OFFER TO (If other than Item 7)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014 TEL: FAX:	W81XWH	See Item 7 TEL: FAX:	

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".

SOLICITATION

9. Sealed offers in original and _____ copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in See Section L until _____ (Hour) local time _____ (Date)

CAUTION - LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE (Include area code) (NO COLLECT CALLS)	C. E-MAIL ADDRESS
	KRISTEN TRUMP	301-619-2346	kristen.trump@us.army.mil

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OFFER (Must be fully completed by offeror)

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT (See Section I, Clause No. 52.232-8)	

14. ACKNOWLEDGMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILITY	16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)

15B. TELEPHONE NO (Include area code)	15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE
	☐		

AWARD (To be completed by Government)

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: ☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )	23. SUBMIT INVOICES TO ADDRESS SHOWN IN (4 copies unless otherwise specified)	ITEM

24. ADMINISTERED BY (If other than Item 7)	CODE	25. PAYMENT WILL BE MADE BY	CODE

26. NAME OF CONTRACTING OFFICER (Type or print) TEL: EMAIL:	27. UNITED STATES OF AMERICA (Signature of Contracting Officer)	28. AWARD DATE

IMPORTANT - Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

Section B - Supplies or Services and Prices

CONTRACT INFORMATION

This requirement is a total set-aside exclusively for Small Business Concerns.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001			Dollars, U.S.		

Clinical Trial Support

CPFF

Support services to conduct federally regulated research requirement to develop new medical products for the Warfighter. Services to include but not limited to: support necessary to conduct clinical trials, analyze resulting data, and generate study reports.

FOB: Destination

MILSTRIP: W74MYF0175N615

PURCHASE REQUEST NUMBER: W74MYF0175N615

ESTIMATED COST

FIXED FEE

TOTAL EST COST + FEE

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
6000		6	Each		

Contractor Manpower Report

FFP

FOB: Destination

NET AMT

Section C - Descriptions and Specifications

WORK STATEMENT

WORK STATEMENT
Definitions:
BLA – Biologics Licensing application
CAP – College of American Pathologists
CFR – Code of Federal Regulations
CLIA – Clinical Laboratory Improvement Act
CO – Contracting Officer
COR – Contracting Officer's Representative
CRF – Case Report Form
CTC – Clinical Trials Center
DOD – Department of Defense
DRA – Division of Regulated Activities
dRAf – Department of Regulatory Affairs
dRL – Department of Regulated Laboratories
ELA – Establishment Licensing Application
FDA – Food and Drug Administration
IND – Investigational New Drug Application
IRB – Institutional Review Board, ensures research is conducted safely and ethically
cGCP – current Good Clinical Practices
cGLP – current Good Laboratory Practices
cGMP – current Good Manufacturing Practices
OHRP – Office of Human Research Protections
PBF – Pilot Bioproduction Facility
PI – Principal Investigator, a physician or scientist who has the primary responsibility for executing a clinical study
PLA Product Licensing Application
SOPs – Standard Operating Procedures
STIGs – Security Technical Implementation Guides
USAMRMC – U.S. Army Medical Research and Materiel Command that is the overseeing Command for WRAIR
WRAIR – Walter Reed Army Institute of Research

Introduction

The Walter Reed Army Institute of Research (WRAIR) requires support services to conduct clinical research studies with experimental medical products under the principles of current Good Clinical Practices (cGCP), Good Laboratory Practices (cGLP), and Good Manufacturing Practices (cGMP). All of the work to support this research must be performed in accordance with the Federal, Department of Defense (DOD), and Command laws, regulations, and policies. Clinical research studies require production of experimental products, conduct of research studies, laboratory analysis of samples, analysis of resulting data, and submission of study findings. The resultant contract will provide support to all of these functions that are largely, but not exclusively, conducted through the Department of Clinical Trials (DCT), Department of Regulatory Affairs (dRAf), Department of Regulated Laboratories (DRL), and the Pilot Bioproduction Facility (PBF) within the Division of Regulated Activities (DRA).

Most products are drugs, devices, or biologics, but research products may include new information and doctrine.

2.0 Background

New vaccines and drugs must undergo closely monitored safety, tolerance, and efficacy studies prior to wider use in field trials. To facilitate the development of new products for military use, DRA was created in October, 2004 to unify the operations required to support the conduct and submission of clinical trials for experimental product development.

The Clinical Trials Center (CTC) was established at the Walter Reed Army Institute of Research (WRAIR) in 1992. The CTC is a non-residential unit configured for early stage clinical trials to be conducted in full compliance with the pertinent regulations of the FDA, OHRP and DoD. Approximately 8 studies are active in any year, most studies enroll 50 to 75 volunteers (the maximum has been 345), and there are an average of 6,000 clinic visits per year. The majority of products tested in the CTC are oriented towards infectious disease agents, but WRAIR scientists also conduct human subjects research in the fields of the neurosciences and combat casualty care. The CTC is staffed by military and approximately 20 contractor personnel.

The following positions have historically been utilized to support the CTC:

Position	Certification	Experience
Senior Coordinator	Registered Nurse, Clinical Research Coordinator or Clinical Research Administrator	Level III Coordinator, At least 3 years clinical trials experience, Managerial and personnel experience
Study Coordinator	Nurse, Clinical Research Coordinator or Clinical Research Administrator	Level III Coordinator with at least 3 years clinical trials experience, able to coordinate complex trial independently
Nurse, Clinical Research Coordinator		Two to four Level II Coordinators with at least 1.5 years clinical trials experience, able to coordinate most studies independently
Nurse		Level I Coordinator with less than 1.5 years of clinical trials experience. Fully capable in a support capacity with desire and ability to become independent Clinical Research Coordinator.
Recruiter		At least one with a year of similar experience. Excellent skills with communications and personal interactions. Competence with MS Office.
Laboratory Manager	National Phlebotomy Association	At least 1 year as a certified phlebotomist with experience in specimen processing, shipping, and archiving.

Specimen Manager	National Phlebotomy Association	At least 6 months as a certified phlebotomist with experience in specimen processing, shipping, and archiving.
Administrative Assistant	Competent with Microsoft Office productivity programs and Quicken	At least 6 months similar job experience. Superb communication and interpersonal skills required.
Information Technologist	Competent in networks, Microsoft Office, Microsoft Access, Microsoft SQL Server; familiarity with Oracle and Study Manager	IT person with at least 3 years of similar job experience. Capable of programming databases, CRF creation – both electronic and hardcopy, and information transfer.
Data Entry	Familiarity with databases that comply with Security Technical Implementation Guides (STIGs); familiarity with commercial-off-the-shelf (COTS) productivity software packages	At least 6 months of similar job experience
Head, Internal Quality Assurance	Clinical Research Administrator, Registered Nurse	At least 5 years experience as a CRA
Internal Quality Monitor	Clinical Research Administrator or Clinical Research Coordinator, Registered Nurse	At least 1.5 yrs experience with monitoring
Clinician Researcher	MD or DO with board certification in primary specialty	Documented experience as a clinical investigator with preference to regulated human subjects research. Excellent organizational skills, analytical and communication skills, initiative, and ability to work independently and in effective teams. cGCP certification highly recommended.
Technical Writer	Bachelor's or Master's degree	Three to five years experience in regulatory medical writing for a pharmaceutical, biotechnology, or contract research company/university medical center, and an understanding of FDA regulatory documentation requirements.

Regulatory Compliance Specialist	Bachelor's or Master's degree	At least three years research and /or regulatory-related work experience
Administrative Support	Undergraduate degree	One to two years of administrative support with experience in managing filing systems, computer records, scientific and medical terminology, and scientific processes.
GLP Technician	Bachelor's or Master's degree	At least three years experience GLP laboratory operations
GLP Technician	Bachelor's or Master's degree	Science background with familiarity in laboratory operations
GLP Laboratory Assistant	Undergraduate degree	Science background with familiarity in laboratory operations

The Department of Regulatory Affairs (dRAf) is an evolving organization that consists of approximately six DoD civilian and contractor personnel. Their mission is to promote compliance with all regulations for medical product development, including pharmaceuticals, biologicals, and devices. They work closely with the regulatory organization at the Medical Research Medical Command (MRMC) level to ensure that all aspects of submissions to regulatory and review agencies are effective, complete, and accurate. The goal of dRAf is to promote the most efficient and successful product approval process.

The Department of Regulated Laboratories (dRL) consists of 3 DoD civilian and approximately 4 contractor personnel to manage a cGLP compliant laboratory equipped to perform assays in accordance with 21 CFR Part 58 for investigators at the WRAIR. The department personnel provides guidance to product development teams on the appropriate level of qualification and validation necessary to support their research goals and then assist or conduct the required analytic work.

3.0 Scope

The purpose of this contract is to provide WRAIR researchers with clinical research support, including qualified contractor personnel, to conduct federally regulated research required to develop new medical products (as defined in the Introduction) for the Warfighter. All of the clinical research support will be within the Division of Regulated Activities. Any research support services that are necessary to conduct clinical trials, analyze resulting data, and generate study reports will be provided through this task upon the approval of WRAIR-reviewed research protocols. This task will be funded incrementally as projects are brought to the departments.

For the purpose of this contract, the contractor will assume that there will be 13 studies per year, with 75 volunteers per study and 6,000 clinic visits.

4.0 Applicable Directives

Services provided under this contract must be conducted in accordance with all Federal, DoD, and MRMC laws, regulations, policies, and procedures that govern the conduct of regulated research. Federal regulations governing cGCP are found in 21CFR 11, 50, 54, 56, 312, and 314 and important guidelines are in the FDA Information Sheets. Additional regulations for human subjects protection are found in 45CFR 46. Those governing cGLP are found in 21 CFR 11 and 58 and WHO (TDR) Quality Practices in

Basic Biomedical Research. EPA cGLP guidelines are covered in 40CFR 160 and 792. The International Convention on Harmonization Guidelines for Good Clinical Practice is also standards governing the conduct of research trials. References for military regulations and policies governing regulated research may be found at https://mrmc.amedd.army.mil/rodorphrpo.asp.

5.0 Performance Requirements

The Contractor shall furnish the necessary personnel (contractor will supervise), equipment, supplies, and transportation to support the performance of the work that enables the WRAIR investigators to perform research at a level of quality to comply with human subjects protection regulations and support successful product development submissions to federal regulatory agencies.

5.1 SUPPORT TO THE DIVISION OF REGULATED ACTIVITIES

5.1.1 Task: Payment to Volunteers

Objective/Outcome: Provide payments to research volunteers for screening or participating in ongoing research studies in accordance with the amounts and schedule specified in each protocol. Payments must be tracked in keeping with all government reporting requirements.

5.1.1.a. Subtask: Provide Payments to CTC Volunteers

Performance Objective: Payment by check shall be distributed to each volunteer at the time of the visit as specified in each protocol. Payments must be available during the normal operating hours of the CTC, generally Monday through Friday between 0630 and 1500 hours. Checks must be drawn on a local financial institution convenient for volunteers to access.

Performance Standards: Volunteers must receive full payment authorized for study visits at the completion of the visit in a form that is safe and convenient.

Measure: Chief, CTC will review full payment records monthly, referencing volunteer identification numbers when reconciling budgetary reports to ensure the correlation between volunteers, dates and defined protocols.

5.1.1.b. Subtask Provide Payments to Volunteers Participating Outside the CTC

Performance Objectives: Payment shall be distributed to each volunteer at the time of the visit as specified in each protocol. Payment will generally be by check, but cash may be used in certain circumstances if required by the locality. Payments must be available during the normal study hours. Checks must be drawn on a local financial institution convenient for volunteers to access.

Performance Standards: Volunteers must receive full payment authorized for study visits at the completion of the visit in a form that is safe and convenient. Cash would only be used after careful review with the COR.

Measure: Chief, CTC will review full payment records monthly, referencing volunteer identification numbers when reconciling budgetary reports to ensure the correlation between volunteers, dates and defined protocols.

5.1.1.c. Subtask: Document Payments to Volunteers

Performance Objectives: The Contractor will track payments with a method that supports review by the COR and Principle Investigators to document correlation between actual visit date and payment date, payment amount, and specific study visit. The Contractor shall issue and disburse payment to each volunteer based on a listing from the COR, or his designee, of all volunteers participating in each study including the amounts and study schedule. Printed reports of payments for invoice purposes or for review outside of study staff must ONLY refer to volunteers by assigned study numbers to maintain confidentiality. The Contractor shall insure proper reporting of study compensation, which is federally taxable income.

Performance Standards: Documentation of volunteer payments must meet requirements of contracting regulations and research confidentiality guidelines. Volunteers must receive all payments in the correct amounts for completed study visits in accordance with the listing of volunteers and study visits provided by the COR or his/her designee. Variation from those standards is not acceptable.

Measures: Chief, CTC will review full payment records monthly, referencing volunteer identification numbers when reconciling budgetary reports to ensure the correlation between volunteers, dates and defined protocols.

5.1.2 Task: Provide Technical Support and Services

Objective/Outcomes: Provide qualified personnel (as shown in the following Personnel Matrix Table) to implement all aspects of clinical trial activities in compliance with human subjects protection regulations and to support a level of quality that will result in successful regulatory submissions for product development. Provide qualified personnel to prepare and manage submissions to regulatory agencies in support of the product development process. Submissions and document management practices will comply with all regulatory requirements and be performed to a level of quality that will result in successful advancement of products in the development process. Provide assistance to support the mission in the form of staffing or specialized services in the cGLP on an as needed basis.

Performance Objectives:The Contractor shall provide qualified staff to prepare and manage the documents required for submissions to the Sponsor and FDA, provide specialized service to dRL in support of their mission to provide laboratory analyses to cGLP standards. Support for general administrative activities as well as technical services, laboratory work, SOP preparation, internal quality reviews, and support of documents required for human subjects protection purposes may also be provided. Examples of regulatory submission support include advising on when regulatory filings are required, the content and scope of the filings, authorship or editing of documents for the submission package, coordination of contributors to the document package, transmitting documents and content to the product Sponsor, and correct procedures for filing and archiving submissions.

Location: The principal place of performance is the WRAIR, located at the Forest Glen Annex, Silver Spring, Maryland. All study activities will be conducted at this and other subordinate field attachments.

All of the nurse coordinators shall be skilled and qualified in nursing procedures including phlebotomy and the administration of experimental vaccines as per specific protocol guidance in accordance with the 21CFR 11, 50, 54, 56, 312, and 314.

The physicians must have unrestricted licenses to practice in Maryland in support of the clinical trials under this requirement. They must meet credentialing requirements as defined by the United States Army Medical Research and Materiel Command (USAMRMC), Clinical Trial Monitoring of Food and Drug Administration (FDA) -Regulated Clinical Trials Policy (Command Policy Memorandum 2011-59), to serve as clinical investigators. This is based on demonstrated experience as a clinical trialist and documented clinical experience as an independent practitioner.

Performance Standards: Implementation of clinical trials in compliance with the protocol, all regulatory standards, and ethical principles. Documents and management processes must comply with all regulatory requirements, both Federal and DoD. Submissions must be made in coordination with the integrated product teams, Sponsor representatives, and participating scientists. Prepared documents must be appropriate for the purpose, accurate in content, and timely in submission. Records of the process and archives of the product must be kept according to quality and applicable standards such as cGCP, cGMP, and cGLP. Contractor personnel providing technical services will be qualified by appropriate education, recent and relevant experience, and certification for the designated services. Information provided about regulatory processes and practices must be accurate, timely, and delivered with good customer service practices. Services will be provided to the level of quality necessary to effectively implement the research mission and within the agreed budget. FDA regulations and MRMC policies specify that personnel involved in clinical trials shall be qualified by experience and training. Variation from these standards is not acceptable.

Professional Licensures and Certifications: All personnel provided by the Contractor who serve in a position that requires a license, certification, and/or registration to perform their duties must maintain a current, active, valid, and unrestricted license or other authorizing document such as certification or registration in accordance with Army Regulation 40-68, Clinical Quality Management issued 26 Feb 2004, WRAIR Policy Letter #06-20, “Initial and Continuing Human Subjects Protection Training for Researchers/Personnel Involved in Human Use Research Protocols,” and USAMRMC Command Policy 2003-01, Licensure, Credentialing and Privileging Program issued 20 February 2003. For the purposes of the resultant contract, the certification must be valid in the location where they fulfill their duties and must be valid at the time of contract award. Licensure, certification, and/or registration requirements apply to professionals performing both clinical and/or administrative duties, and the regulations specifically include personnel working within USAMRMC.

Measures: Product Sponsor and Product Development representatives will review all submissions. Documents will be audited by internal and external quality monitors. Success is assessed as acceptance by the FDA and positive review of information presented in the submission package. No more than one position per year should turnover because of significant training requirements and the negative impact on mission when continuity is lost.
Documented compliance with CTC SOPs including training with SOPs, compliance with SOPs, and required maintenance of SOPs. Documented maintenance of all specified certifications and licenses. Documented continuing education in professional field (such as nursing) to maintain quality of technical skills. Documented continuing education in cGCP and human subjects protection to maintain quality of research and compliance with evolving regulations. Protocol specific deviation reports and results of internal and external monitoring and audits. All work done at the cGLP would be reviewed by Chief, DRL, QA/QC personnel, and the COR. Review of services and outputs by the COR monthly to ensure quality and applicability, and arewithin agreed budgets.

Records of training, certifications, and licensure shall be maintained onsite for verification by COR and appropriate WRAIR personnel supervising the conduct of regulated research. Proof of liability coverage, including tail coverage for the physicians, must be available from the contractor. Study deviation reports will be tracked for patterns of non-compliance. Research studies are monitored and audited by external Sponsor representatives. Those reports will be reviewed monthly for patterns of error or non-compliance.

5.1.3 Task: Recruiting and Advertising

Objective/Outcome: Sufficient numbers of healthy, qualified volunteers are enrolled to meet the requirements of clinical studies.

Performance Objective: The Contractor shall devise recruiting strategies to identify potential research volunteers, provide valid estimates of their cost, and implement them. Recruiting is one of the greatest challenges facing clinical trials facilities in this geographic area, and the CTC needs approximately 400 volunteers to enroll in studies each year. The Contractor shall have the capability of designing and producing effective advertising products to be used in modern media venues. Advertising must be done within defined study budget parameters as well advertisement and recruiting materials meeting ethical guidelines.

Performance Standards: 98% of required, qualified volunteers are enrolled for each study. Advertising expenses do not exceed the budgeted amount. All advertising materials are approved by mandatory ethical review processes as described in federal and local regulations.

Measurement: Weekly recruiting meetings to review recruiting goals and enrollment success. Recruiting budgets are reconciled and reviewed with the COR at the end of the recruiting phase.

5.1.4 Task: Provide Meals and Beverages

Objective/Outcome: Attractive and appetizing beverages and food shall be provided for volunteers within defined study budgets.

Performance Objective: The Contractor shall furnish beverages and snacks (i.e. juices, coffee, cookies, pastries, etc.) for volunteers with prolonged visits in the CTC. Additionally, in the event of extended observation periods or during residential studies offsite, the Contractor shall provide meals to ensure the comfort and safety of the volunteers participating in the defined research activities. The COR, or his designee, shall determine when to provide these services and advise on items to be provided.

Performance Standards: Volunteer acceptance and enjoyment of food provided as evidenced by no more than one complaint per month regarding refreshments. Active solicitation of volunteer satisfaction and preferences are encouraged.

Measures: Volunteer complaints, review of invoices to confirm expenses are within budget allowances, review of items set out for volunteers.

5.1.5 Task: Arrange Conferences and Seminars

Objective/Outcome: Organize successful conferences and seminars that provide effective training within specified budget.

Performance Objective:The Contractor shall provide all the necessary services, qualified personnel, materials and facilities, not otherwise provided by the government, needed for the successful planning and execution of meetings, workshops, seminars, training, etc., sponsored or organized through the CTC. The contractor shall arrange for any certifications required for the training, such as qualifying for continuing medical education credits, cardiopulmonary resuscitation exercises, and/or cGCP certification. The Contractor shall obtain satisfaction evaluations from the attendees. All aspects of planning and implementing meetings, workshops, seminars, etc., shall be undertaken in coordination with the COR.

Performance Standard: For training session providing certificates, the content and teaching quality shall be such that at least 95% of attendees will achieve certification standards. 90% of speakers shall receive evaluations of at least 90% satisfactory or better. Results of attendee evaluations will be reflected in subsequent planning to improve future events. Expenditures for conferences will not exceed budget.

Measures: Invoices shall be reviewed to confirm expenses are within budget. Certification rates and attendee satisfaction surveys will be reviewed by the COR after every conference.

5.1.6 Task: Arrange Hotel/Residential Accommodations

Objective/Outcome: Arrange off site accommodations necessary to implement residential research studies or respond to emergencies closing on-post facilities.

Performance Objective: The CTC implements research protocols that require residential monitoring of volunteers. In those cases, the Contractor shall provide all necessary support and make all appropriate arrangements to secure the needed accommodations to house the volunteers and support personnel required to fully comply with protocol procedures. Previously, these settings have been hotels, but other facilities could be used based on the needs of individual research studies. In the event of an emergency that makes the CTC unavailable to volunteers, the Contractor shall identify an alternate location and facilitate moving operations to continue the research mission. Any off site location must be approved by the COR in advance of the research activity.

Performance Standard: Facilities obtained for research studies outside of WRAIR shall be clean, safe, and convenient for volunteers and staff. They shall accommodate all procedures necessary to implement the protocol. The cost of facilities shall not exceed the previously agreed study budget by more than 5%. No more than 2 complaints from volunteers or staff regarding the facilities per 5-day period is acceptable.

Measures: Review of invoices monthly to verify expenses are within budget. Review of any complaints by COR concurrently with off site activity. Concurrent review of any protocol deviations occurring offsite for any indication that inadequacy of the site is causing noncompliance.

5.1.7 Task: Clinical Laboratory Services

Objective/Outcome: The Contractor provides CAP/CLIA-certified clinical laboratory testing to support research studies with turnaround times and reporting methods equivalent to a standard clinical setting (in accordance with 21CFR 11, 50, 54, 56, 312, and 314). Obtain supplies and equipment essential to the mission of conducting cGLP testing in a cost effective and timely manner.

Performance Objective:The Contractor shall provide, either directly or through subcontracting, CAP/CLIA certified laboratory support services and the necessary supplies to carry out clinical laboratory testing described in protocols. Research studies may require esoteric laboratory tests available only from highly specialized vendors in addition to routine clinical tests. Obtain critical supplies for the GLP essential to the conduct of the research mission quickly that meet specifications in accordance with the approved protocol, agreed upon by the COR.

Performance Standard: Clinical laboratory analyses are performed in complete compliance with CAP/CLIA regulations. Samples are picked up at the collection site, including off site locations, at times compatible with protocol schedules. Results are available within time periods accepted in a standard hospital setting. Results are provided by methods that are accepted in a standard hospital setting. Results are provided according to sample identification procedures defined in the protocols. Any type of error with lab samples shall not exceed one per month. Laboratory services charges do not exceed the previously agreed amounts in study budgets. Supplies or equipment of the desired quality and capability arrive within the timeframe specified by the COR within the agreed upon estimate.

Measures: CAP/CLIA certifications are provided annually to the Chief of CTC, along with the Crriculum Vtae (CV) from the laboratory director as required by FDA regulations. Invoices with laboratory charges shall be reviewed monthly by the COR. Results are reviewed daily by study staff for each protocol. Errors with results or sample processing are reviewed by the COR concurrently.

5.1.8 Task: Provide Portable Phones and/or Pagers

Objective/Outcome: The Contractor provides cellular telephone and/or pager communication devices to investigators and study staff as needed to support effective communications during research studies.

Performance Objective: The contractor will provide means of dependable communication as determined by the COR to support protocols when needed.

Performance Standard: The contractor will provide equipment for dependable communication to appropriate study as determined by the COR based on needs of individual study protocols and the CTC mission. No more than one volunteer or staff complaint monthly that a contact was missed.

Measures: COR review of invoices monthly for accumulated costs. Concurrent reports by study staff for communications needs. Complaints by volunteer or study staff of failed communications.

5.1.9 Task: Design and Print Study Form

Objective/Outcome: Provide source documents and case report forms for studies meeting data collection needs of each protocol.

Performance Objective: When needed for a study, contract study staff will work with teams of Investigators and Sponsor personnel to design study forms that collect data required for studies. The forms shall be designed to promote accuracy and ease of data entry. The Contractor will provide printed forms in a format that promotes efficient and accurate data entry. The Contractor will ensure processes exist to quickly revise forms when required and provide printed replacements.

Performance Standard: Forms will meet Sponsor specifications for data entry and FDA regulations for submissions. Costs to produce study forms will not exceed budget agreed with COR.

Measures: Forms will be reviewed monthly by Principle Investigators, Command Quality staff, and Sponsor personnel for acceptability. COR will review invoices to confirm that costs do not exceed budget.

5.1.10 Task: Provide Data Management Services

Objective/Outcome: Produce, analyze, report, and archive data to support FDA submissions when needed to support the research mission.

Performance Objective: When requested by the COR to support specific studies, the Contractor will provide data management services to include at a minimum: 1) assisting with a data management plan, 2) creating databases using a standard commercial-off-the-shelf (COTS) database program that is STIGs-compliant, 3) creating data support documentation, 4) data entry, 5) data validation, 6) data query generation and resolution, 7) generating data tables, and 8) archiving data to Command agency standards.

Performance Standard: All data management practices will comply with regulatory standards required to support FDA submissions in 21CFR 11, 50, 54, 56, 312, and 314. By 20011 the Contractor capability will comply with electronic data submission requirements. No variation is acceptable. Costs will be within budget agreed with COR.

Measures: Internal and external monitoring and auditing of data by Investigators, Sponsor, Quality, and Regulatory personnel. COR will review invoices monthly to ensure that costs do not exceed budget by more than 5%.

5.1.11 Task: Provide Statistical Support Services

Objective/Outcome: Provide statistical services to support the design, implementation, analysis, and reporting of research protocols.

Performance Objective: When directed by the COR to support specific protocols, the Contractor will provide statistical services to support the research mission that will include, at a minimum:1) assisting in developing the statistical plan for a protocol including power calculations 2) preparing randomization schemes and tables 3) assisting in CRF review, design, and preparation 4) analyzing data sets and provide results as needed by the study team 5) providing training to CTC staff as neededand 6) assisting in writing statistical portions of study reports and manuscripts

Performance Standard: All statistical services will comply with the protocol procedures, Sponsor requirements, and regulatory standards to support FDA submissions. No variation is acceptable. Costs will be within budget agreed with COR.

Measures: Internal and external review of statistical products by Investigators, Sponsors, Quality, and Regulatory personnel. COR will review invoices to ensure that costs do not exceed budget by more than 5%.

5.1.12 Task: Provide Study Supplies

Objective/Outcome: Provide supplies meeting the specifications required to implement research studies on a timely basis within study budgets.

Performance Objective: At the direction of the COR, the Contractor will obtain supplies necessary to implement research studies. The COR will verify receipt of the requested items and their acceptability.

Performance Standard: Supplies will meet the standards specified by the COR and be of a quality that will produce results in keeping with cGCP standards. Supply purchases will be made in keeping with federal contracting regulations. The cost of purchased supplies will not exceed the amounts previously agreed to by the COR.

Measures: COR or their designee will inspect supplies upon receipt for compliance with protocol specifications. COR will review invoices monthly to ensure that costs do not exceed previously- agreed estimates.

5.1.13 Task: Arrange and Fund Travel for Contract Personnel

Objective/Outcome: Contract personnel will travel to and participate in required conferences at the direction of the COR.

Performance Objective: The Contractor shall arrange for travel of support personnel at the request of the COR when it is necessary to support research studies and the CTC. Most travel is expected to occur within the continental United States (CONUS), but travel may extend outside of the continental United States (OCONUS) . The Contractor must provide for all necessary travel documents, immunizations, and safety plans that may be required for some destinations. All travel costs will be paid in accordance with the Joint Travel Regulation per diem and housing rates. The contractor must provide an invoice for travel expenses and, if requested, copies of receipts.

Performance Standard: Travel will be arranged in accordance with requests and specifications of the COR. Travel arrangements will ensure that personnel are at the Conference location and able to fully participate as needed to serve the research mission. Travel costs will not exceed previously agreed amounts by more than 5%.

Measures: COR review of invoices monthly for travel costs to ensure that amounts are within budget.

5.1.14 Task: Provide Training

Objective/Outcome: Contractor personnel will be fully qualified technically to serve the research mission and will participate in continuing education, both for research and specialty areas, to ensure that the quality of their skills remains high and their knowledge base reflects the most up to date information.

Performance Objective: The Contractor shall ensure that support personnel receive appropriate training to maintain their skills and certifications necessary to provide the required services within the CTC. Training courses for support personnel may be offered at the WRAIR site with the approval of the COR.

Performance Standard: When appropriate, accredited training programs providing certifications will be used. 95% of personnel attending accredited programs will achieve certification. Training must be coordinated in advance with the COR and then approved by the COR prior to the Contractor incurring

the cost. Training costs must be within the budget agreed upon with the COR. Professional employees must maintain valid licenses and certifications.

Measures: Review of training records by COR or designee monthly as required under cGCP. Review of licenses and professional certifications by COR or designee monthly.

5.1.15 Task: Provide Supplies and Equipment

Objective/Outcome: Obtain supplies and equipment essential to the mission of conducting GCP studies in a cost effective and timely manner.

Performance Objective: Obtain critical supplies essential to the conduct of the research mission quickly that meet specifications agreed upon with the COR.

Performance Standards: Supplies or equipment of the desired quality and capability arrive within the timeframe specified by the COR within the agreed upon estimate.

Measures: Review of invoices and receiving reports by the COR.

5.2 Major Task Area: Support Command Safety Priorities

Objectives/Outcome: All Contractor personnel located within WRAIR shall perform their duties in full compliance with MRMC and WRAIR Safety policies in accordance with MRMC Command Policy Memorandum 2009-39 (Commander's Safety Policy).

Performance Objectives: All Contract personnel will be familiar with and observe the safety and standard operating procedures established to cover work within their areas of the facility. Contract employees shall participate in all required safety training and apply the lessons in all aspects of their work activities.

Some projects may require immunization with licensed or experimental vaccines for the protection of potentially exposed personnel. When appropriate, WRAIR will offer the experimental vaccines at no cost to the Contractor and provide enrollment into the appropriate safety protocol for the recipient. If a licensed vaccine is available, the Contractor must provide the vaccination through its internal occupational safety program. The Contractor must assure that employees only receive vaccines on a voluntary basis; however, for some projects with specific agents, unvaccinated employees will not be allowed to participate. Needs for vaccination will be discussed between the COR, the Contractor, and the Contractor's occupational safety specialist. Hepatitis B vaccination and annual influenza vaccination are encouraged for all employees.

Performance Standards: Maintain 100% rating on department safety inspections. No more than one accident per year in the Division. When the COR has notified the Contractor that a project requires immunization to protect workers, no Contract personnel may participate without effective immunization. The Contractor will offer personnel annual influenza and Hepatitis B immunization.

Measures: Monthly departmental safety inspections are reviewed by the Division Director and reported to the COR. Reports of safety events are reviewed by the Division Director and COR. Immunization

records, when required for worker protection, will be reviewed by the Chief, CTC, prior to personnel working with specific agents.

6.0 Reporting Requirements and Deliverables

6.1 Monthly Invoices – The Contractor shall provide monthly invoices according to federal acquisition regulations that reflect work performed by Task and Subtask using a format that will facilitate accurate review and assessment by the COR of actual work performed and cost.

6.2 Reports required to support the CTC:

6.2.1. Monthly reports that will be submitted within the first 15 days of each month:
Monthly recruitment summary table
Monthly visits summary table
CTC Monthly update report

6.2.2. The Contractor will provide an annual report during January of each year that summarizes for the preceding year the studies implemented, the studies completed, a list of studies that were active, and summary statistics for screening, enrollment, and participation (including demographic information).

6.2.3. As each study achieves milestones, such as completion of enrollment or last study visit, the Contractor shall provide a report to the COR summarizing the work completed to support the study. This shall include, at a minimum, the number of volunteers recruited, briefed, and screened; the total amount of advertising; the amount of volunteer compensation; the level of personnel effort; the quantity of laboratory testing; and the value of purchased supplies. Milestones for each study shall be determined by the COR and communicated to the Contractor.

CLAUSES INCORPORATED BY REFERENCE

USAMRAA 52.009-4004	ORGANIZATIONAL AND CONSULTANT CONFLICTS OF INTEREST (MAR 1999) (USAMRAA)	MAR 2007

CLAUSES INCORPORATED BY FULL TEXT

SAFEGUARDING PROPRIETARY INFORMATION (MAY 1999) (USAMRAA)

a. "Proprietary information" shall mean all information, whether disclosed orally, in writings, by drawings, or otherwise relating to the work to be performed under this contract, whether proprietary to the Government or one of its collaborating partners. Proprietary information includes, but is not limited to, information regarding properties,

formulae, structures, manufacturing processes, and test results. Information ceases to be proprietary when it is generally available to the public or is available from sources other than the Department of the Army. All information submitted to the contractor under this contract shall be presumed to be proprietary to the Department of the Army or one of its collaborating partners until the Department of the Army announces to the contrary.

b. The contractor shall safeguard proprietary information both during and after the term of this contract, and shall neither appropriate, nor disclose, nor make unauthorized use of the proprietary information received under this contract. The requirements of this paragraph include, but are not limited to, the following:

(1) Maintenance of a high degree of physical security over proprietary information at all times;
(2) Discussion of proprietary information only among contractor's employees whose duties and responsibilities require knowledge of that information; and,
(3) Elimination of proprietary information in open publications by the contractor and its personnel.

c. The contractor shall require all personnel who receive proprietary information to execute the statement in paragraph d below when this contract becomes effective or when first employed (if employed after the contract becomes effective). All statements executed pursuant to this paragraph shall be forwarded to the U.S. Army Medical Research Acquisition Activity when this contract terminates, when the employment ends, or upon request of the Contracting Officer.

d. The following statement shall be executed pursuant to paragraph c above:

I hereby acknowledge that I have been informed that my duties may require that I have access to proprietary information. I understand this proprietary information which I will receive includes, but is not limited to, properties, formulae, structures, protocols, manufacturing processes, and test results.

I agree that I will neither appropriate nor disclose nor make unauthorized use of proprietary information both during and after my employment. I further agree that I will neither include nor draw upon proprietary information received under this contract in open publication. This agreement is executed with the intention that collaborating partners of the United States Government who have submitted information to the Government under non-disclosure obligations shall be third party beneficiary hereunder, and shall have the right to enforce the obligations undertaken herein.

Name:
Date:

e. The contractor shall insert the substance of paragraphs a through d above in each subcontract hereunder. Compliance with the provisions of this clause shall be the responsibility of the contractor.

GOOD LABORATORY PRACTICES (DEC 2006) (USAMRAA)

The conduct of studies on investigational new drugs or devices shall comply with the GOOD LABORATORY PRACTICE (GLP) FOR NONCLINICAL LABORATORY STUDIES regulations 21 CFR 58. The contractor shall notify the Administrative Contracting Officer by telephone immediately upon announcement by a representative of the Food and Drug Administration (FDA) of an inspection of studies performed under this contract. In addition to the FDA representative, the Contracting Officer's Representative (COR) shall have access to the contractor's records and specimens. With reference to paragraph 58.195(h) of the GLP regulations, the contractor shall notify the COR in writing in addition to the FDA, should the contractor go out of business and/or transfer the records during the periods prescribed in paragraph 58.195. On expiration or termination of the contract, the contractor shall notify the COR of any remaining unused test articles.

USE OF TECHNICAL REFERENCE FACILITY (APR 2005) (USAMRAA)

The contractor agrees to use**,** to the extent practical**,** the technical reference facilities of the Defense Technical Information Center (DTIC) for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. The DTIC headquarters office is located at 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218. Information can also be obtained via the Internet at http://www.dtic.mil or via the toll-free number for the DTIC help desk, 1-800-225-3842. To the extent practical, all other sources, whether or not Government controlled, should be consulted for the same purpose.

INVESTIGATING AND REPORTING POSSIBLE SCIENTIFIC MISCONDUCT (MAR 1999) (USAMRAA)

a. "Misconduct" or "Misconduct in Science" is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

b. Contractors shall foster a research environment that prevents misconduct in all research and that deals forthrightly with possible misconduct associated with research for which U.S. Army Medical Research and Materiel Command funds have been provided or requested.

c. The contractor agrees to:
(1) Establish and keep current an administrative process to review, investigate, and report allegations of misconduct in science in connection with research conducted by the contractor;
(2) Comply with its own administrative process;
(3) Inform its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures;
(4) Take immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged; and
(5) Report to the Administrative Contracting Officer (ACO) a decision to initiate an investigation into possible scientific misconduct.

d. The contractor is responsible for notifying the ACO of appropriate action taken if at any stage of an inquiry or investigation any of the following conditions exist:
(1) An immediate health hazard is involved;
(2) There is an immediate need to protect Federal funds or equipment;
(3) A probability exists that the alleged incident will be reported publicly; or
(4) There is a reasonable indication of possible criminal violation.

52.035-4030 CONTRACTOR SAFETY AND REPORTING (NON-BDRP) (DEC 2006) (USAMRAA)

a. The contractor shall operate under established safety programs for all biosafety levels of work as identified in the Safety Program Plan, which is incorporated in this contract. The safety programs shall ensure that personnel, facilities, and the environment are protected from accidents and hazardous exposures.

b. The contractor shall conduct this contract work under established operating procedures which ensure that all individuals who have access to areas for storage, handling, and disposal of etiologic agents are trained and are thoroughly familiar with safety requirements. Such procedures shall assure full compliance with the regulatory standards cited above.

c. The contractor shall conduct an inspection and report the results of all required biosafety inspections for all Research, Development, Test, or Evaluation work in accordance with the below listed timeframes. As a minimum the safety inspections shall address those factors identified in the Safety Program Plan.

1. For Biosafety Level (BL) 1 and 2:

Time	Inspector
Preaward	Government designated Biosafety Officer
Quarterly	Contractor safety personnel
Weekly	First line supervisor

2. For Biosafety Level (BL) 3:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	Contractor safety personnel
Annual	Government designated Biosafety Officer
Weekly	First line supervisor

3. For Biosafety Level (BL) 4:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	Contractor safety personnel
Annual	Government designated Biosafety Officer
Weekly	First line supervisor

4. Copies of all biosafety inspection reports will be distributed as follows:

Original: In the contractor's records

One copy to the following:

a. US Army Medical Research and Materiel Command
ATTN: MCMR-ZC-SSE
504 Scott Street
Fort Detrick, Maryland 21702-5012

b. US Army Medical Research and Materiel Command
ATTN: MCMR-ZB-DRI
504 Scott Street
Fort Detrick, Maryland 21702-5012

c. US Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-W
820 Chandler Street
Fort Detrick, Maryland 21702-5014

PROHIBITION OF HUMAN RESEARCH (JAN 2007) (USAMRAA)

**** PROHIBITION – READ FURTHER FOR DETAILS ****

Research under this award involving the use of human subjects, to include the use of human anatomical substances and/or human data, may not begin until the US Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the Contractor. A copy of the approval will be provided to the US Army Medical Research Acquisition Activity for the official file. Non-compliance with any provisions of this clause may result in withholding of funds and or the termination of the award.

USE OF HUMAN SUBJECTS (FEB 2002) (USAMRAA)

a. The contractor or its subcontractors, are authorized to conduct research under this award involving humans as research subjects for the following protocols:

Protocols not identified are not approved.

b. Contractors and subcontractors are required to submit documentation of IRB review of protocols and consent forms from each of the funded institutions. Research at funded institutions may not begin until the U.S. Army Surgeon General's Human Subjects Research Review Board (HSRRB) approves the protocol and consent form for that site. Review by the HSRRB is separate from, and in addition to, review by any other IRB. Contractors will be notified in writing of HSRRB approval or disapproval.

c. Contractors and subcontractors who enroll additional unfunded institutions are responsible to ensure that the institute conducts research in accordance with 45 CFR 46 and other applicable federal and state regulations. Prior to inclusion of any unfunded institution's participation under this award, the contractor is responsible to notify the Contracting Officer.

d. Volunteer Registry Data Sheet (USAMRDC Form 60-R). In accordance with the "Use of Human Subjects" provision above, the Volunteer Registry Data Sheet, USAMRDC Form 60-R (form available on web site http://www.usamraa.army.mil)is to be completed at the time the subject consents to participate and is entered into the study. The form shall be submitted to the Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012 upon completion of the research project or upon expiration/termination of the award, whichever occurs first.

e. Unless the research has been ruled exempt from the requirements of the Federal Common Rule (32 CFR 219) by the HSRRB, the local IRB is required to conduct continuing review of the contractor's research at least annually, or more often if the local IRB deems it necessary, in accordance with the Federal Common Rule. Pursuant to Office for Human Research Protections guidance, contractors must submit the following to the local IRB for continuing review: a protocol summary and status report on the progress of the research, including (1) the number of subjects accrued; (2) a description of any adverse events or unanticipated problems involving risks to subjects or other and of any withdrawal of subjects from the research or complaints about the research; (3) a summary of any recent literature, findings obtained thus far, amendments or modifications to the research since the last review, reports on multi-center trails and any other relevant information, especially information about risks associated with

the research; and (4) a copy of the current informed consent document. **Contractors are required to submit all continuing review reports, and the final report approved by the local IRB, to the HSRRB within seven working days of each review. Submissions to the HSRRB should be sent to: Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012. Submissions may also be faxed to: 301-619-7803 (ATTN: MCMR-RCQ-HR).**

f. The contractor must submit any proposed modifications or amendments to the protocol or consent form to both the local IRB and the HSRRB for review and approval. A change of the Principal Investigator is considered to be a modification of the protocol. Research pursuant to such modifications or amendments may not be initiated without IRB and HSRRB approval except when necessary to eliminate apparent immediate hazards to the subject(s).

g. Single Project Assurance. The contractor's Single Project Assurance, dated _____, is incorporated by reference and is assigned number _____.

USE OF LABORATORY ANIMALS (CONUS)(MAR 2002) (USAMRAA)

a. The contractor or its subcontractors, are authorized to conduct research under this award involving laboratory animals for the following protocols:

Protocols not identified are not approved.

b. ANIMAL WELFARE

(1) For those facilities that are required to do so by federal law, the contractor shall register its research facility with the Secretary of Agriculture in accordance with 7 U.S.C. 2136 and 9 CFR, Subchapter A, Part 2, Subpart C, and Section 2.30.

(2) The contractor shall acquire regulated animals only from dealers licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR, Subchapter A, Part 2, Subpart A, Sections 2.1 through 2.11, or from sources that are exempt from licensing under those sections.

(3) The contractor agrees that the care and use of animals will conform with the pertinent laws of the United States and regulations of the Department of Agriculture (see 7 U.S.C. 2131 et.seq. and 9 CFR Subchapter A, Parts 1 through 4), and that the research will adhere to the principles set forth in the Guide for Care and Use of Laboratory Animals, National Research Council, 1996.

(4) The Contracting Officer may immediately suspend, in whole or in part, work and further payments under this award for failure to comply with the requirements of paragraphs (1) through (3) of this clause.

(a) The suspension will stay in effect until the contractor complies with the requirements.

(b) Failure to complete corrective action within the time specified by the Contracting Officer may result in termination of this award and removal of the contractor's name from the list of facilities approved for funding.

(5) The contractor may request registration of its facility and a

current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), for the region in which its research facility is located. The location of the appropriate APHIS regional office, as well as information concerning this program may be obtained by contacting the Senior Staff Officer, Animal Care Staff, USDA/APHIS, Animal Care, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 (Phone number 301-734-4981 or email ace@usda.gov).

(6) The contractor shall include this clause, including this paragraph (6), in all subcontracts/subawards involving research of live vertebrate animals.

c. POST-AWARD OVERSIGHT OF THE USE OF LABORATORY ANIMALS

Post-award oversight of the use of laboratory animals shall be the responsibility of the contractor's Animal Care and Use Committee (ACUC). The Principal Investigator will notify the Contracting Officer in writing of any significant changes to the proposed use of animals which was the basis for award. These changes must be approved by the contractor's ACUC and the USAMRMC. In addition, the ACUC shall immediately notify the Contracting Officer of any violations of law, or regulation involving animal care, or of changes in the facility's accreditation status by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

d. ANIMAL USE REPORTING

(1) The contractor shall annually prepare and electronically submit the U.S. Army Medical Research and Materiel Command Animal Use Report detailing the use of animals in the research and development sponsored by the Army. The web site containing information for electronic submission of this report may be found at http://www.usamraa.army.mil.

(2) A letter with additional instructions concerning use of the electronic web site will be mailed at the end of the fiscal year. The reporting period shall be each Federal Fiscal Year, i.e., 01 October through 30 September, and the report shall be electronically received by the U. S. Army Medical Research and Materiel Command **no later than 1 December of that year**.

(3) For awards with expiration dates prior to 30 September, instructions for submission of the final animal use report may be found at http://www.usamraa.army.mil.

(4) The contractor shall also furnish a copy of the most recent USDA Inspection Report. This report can be submitted via fax or mail to:

Commander
U.S. Army Medical Research & Materiel Command
ATTN: MCMR-RCQ-AR
504 Scott Street
Fort Detrick MD 21702-5012
FAX: (301) 619-4165

(5) The contractor is responsible for ensuring that a separate U.S. Army Medical Research and Materiel Command Animal Use Report and USDA Inspection Report be submitted for any subcontract/subaward facility).

52.035-4036 PROHIBITION OF USE OF HUMAN CADAVERS (JAN 2005) (USAMRAA)

**** PROHIBITION – READ FURTHER FOR DETAILS****

Research under this award using human cadavers may not begin until the US Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human cadavers under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the Contractor. A copy of this approval will be provided to the US Army Medical Research Acquisition Activity for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award.

REPORTS, MANUSCRIPTS AND PUBLIC RELEASES (DEC 2006) (USAMRAA)

a. Contractors are encouraged to publish results of research supported by the US Army Medical Research and Materiel Command (USAMRMC) in appropriate media forum. Any publication, report or public release, which may create a statutory bar to the issuance of a patent on any subject invention, shall be coordinated with appropriate patent counsel.

b. Manuscripts intended for publication in any media shall be submitted to the Contracting Officer and Contracting Officer's Representative (COR), simultaneously with submission for publication. Review of such manuscripts is for comment to the Principal Investigator, not for approval or disapproval. Courtesy copies of the reprint shall be forwarded to the Contracting Officer and COR, even though publication may be subsequent to the expiration of the contract.

c. The Contractor shall notify the Contracting Officer of planned news releases, planned publicity, advertising material concerning contract work, and planned presentations to scientific meetings, prior to public release. This is not intended to restrict dissemination of research information but to allow USAMRMC advance notice in order to adequately respond to inquiries.

d. Manuscripts, reports, public releases and abstracts, which appear in professional journals, media and programs, shall include the following statements:

(l) "This work is supported by the US Army Medical Research and Materiel Command under Contract No.__TBD____"

(2) "The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation."

(3) As applicable, if the research involves the use of animals, the Contractor must include the following statement: "In conducting research using animals, the investigator(s) adhered to the Animal Welfare Act Regulations and other Federal statutes relating to animals and experiments involving animals and the principles set forth in the current version of the Guide for Care and Use of Laboratory Animals, National Research Council."

(4) As applicable, if the research involves human use, the Contractor must include the following statement: "In the conduct of research where humans are the subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects)."

(5) As applicable, if the research involves the use of recombinant DNA, the Contractor must include the following statement: "In conducting work involving the use of recombinant DNA the investigator(s) adhered to the current version of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules."

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
6000	Destination	Government	Destination	Government

CLAUSES INCORPORATED BY REFERENCE

52.246-8	Inspection Of Research And Development Cost Reimbursement	MAY 2001

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	POP 01-SEP-2011 TO 31-AUG-2016	N/A	WALTER REED ARMY INSTITUTE OF RESEARCH COL JAMES CUMMINGS ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 301-319-9887 FOB: Destination	W74MYF
6000	N/A	N/A	N/A	N/A

CLAUSES INCORPORATED BY REFERENCE

52.242-15	Stop-Work Order	AUG 1989
52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I	APR 1984
52.247-34	F.O.B. Destination	NOV 1991

Section G - Contract Administration Data

CLAUSES INCORPORATED BY FULL TEXT

PAYMENT INSTRUCTIONS FOR MULTIPLE ACCOUNTING CLASSIFICATION CITATIONS (JULY 2006) (USAMRAA)

____ (1) *Line item specific: single funding*. If there is only one source of funding for the contract line item (i.e., one ACRN), the payment office will make payment using the ACRN funding of the line item being billed. CLIN _____

____ (2) *Line item specific: sequential ACRN order*. If there is more than one ACRN within a contract line item, the payment office will make payment in sequential ACRN order within the line item, exhausting all funds in the previous ACRN before paying from the next ACRN using the following sequential order: Alpha/Alpha; Alpha/numeric; numeric/alpha; and numeric/numeric. CLIN _____

____ (3) *Line item specific: contracting officer specified ACRN order*. If there is more than one ACRN within a contract line item, the payment office will make payment within the line item in the sequence ACRN order specified by the contracting officer, exhausting all funds in the previous ACRN before paying from the next ACRN. CLIN _____

____ (4) *Line item specific: by fiscal year*. If there is more than one ACRN within a contract line item, the payment office will make payment using the oldest fiscal year appropriations first, exhausting all funds in the previous fiscal year before disbursing from the next fiscal year. In the event there is more than one ACRN associated with the same fiscal year, the payment amount shall be disbursed from each ACRN within a fiscal year in the same proportion as the amount of funding obligated for each ACRN within the fiscal year. CLIN _____

____ (5) *Line item specific: by cancellation date*. If there is more than one ACRN within a contract line item, the payment office will make payment using the ACRN with the earliest cancellation date first, exhausting all funds in that ACRN before disbursing funds from the next. In the event there is more than one ACRN associated with the same cancellation date, the payment amount shall be disbursed from each ACRN with the same cancellation date in the same proportion as the amount of funding obligated for each ACRN with the same cancellation date. CLIN _____

____ (6) *Line item specific: proration*. If there is more than one ACRN within a contract line item, the payment office will make payment from each ACRN in the same proportion as the amount of funding currently unliquidated for each ACRN.
CLIN _____

____ (7) *Contract-wide: sequential ACRN order*. The payment office will make payment in sequential ACRN order within the contract, exhausting all funds in the previous ACRN before paying from the next ACRN using the following sequential order: alpha/alpha; alpha/numeric; numeric/alpha; and numeric/numeric.

____ (8) *Contract-wide: contracting officer specified ACRN order*. The payment office will make payment in sequential ACRN order within the contract, exhausting all funds in the previous ACRN before paying from the next ACRN in the sequence order specified by the contracting officer.

____ (9) *Contract-wide: by fiscal year*. The payment office will make payment using the oldest fiscal year appropriations first, exhausting all funds in the previous fiscal year before disbursing from the next fiscal year. In the event there is more than one ACRN associated with the same fiscal year, the payment amount shall be disbursed from each ACRN within a fiscal year in the same proportion as the amount of funding obligated for each ACRN within the fiscal year.

____ (10) *Contract-wide: by cancellation date*. The payment office will make payment using the ACRN with the earliest cancellation date first, exhausting all funds in that ACRN before disbursing funds from the next. In the event there is more than one ACRN associated with the same cancellation date, the payment amount shall be disbursed from each ACRN with the same cancellation date in the same proportion as the amount of funding obligated for each ACRN with the same cancellation date.

____ (11) *Contract-wide: proration*. The payment office will make payment from each ACRN within the contract in the same proportion as the amount of funding currently unliquidated for each ACRN.

___X__ (12) *Other*. . If there is more than one ACRN within a contract line item, the payment office will make payment using the oldest fiscal year appropriations first, exhausting all funds in the previous fiscal year before disbursing from the next fiscal year. In the event there is more than one ACRN associated with the same fiscal year, the payment amount shall be disbursed from the oldest CLIN within the fiscal year.

REPRESENTATIONS AND CERTIFICATIONS (MAR 1999) (USAMRAA)

The representations, certifications, and other statements submitted by the contractor, dated TBD, are incorporated herein by reference.

TRAVEL (JULY 2007) (USAMRAA)

a. Approval of Foreign Travel. The cost of foreign travel is allowable only when the specific written approval of the Contracting Officer is obtained prior to commencing the trip. Approval shall be requested at least (Insert number of days--suggest 90-120) calendar days before the scheduled departure date in order that all necessary clearances may be processed. Each individual trip must be approved separately, even though it may have been included in a previously approved budget. Foreign travel under this contract is defined as any travel outside of the United States and its territories and possessions.

b. Costs incurred by contractor personnel on official company business, whether foreign travel and/or domestic/local travel, are allowable, subject to the limitations contained in the Federal Acquisition Regulation (FAR) clause at 52.216-7, Allowable Cost and Payment, incorporated into this contract.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUL 2004
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	OCT 2010
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	JAN 1997
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	OCT 2010
52.204-4	Printed or Copied Double-Sided on Recycled Paper	AUG 2000
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	JUL 2010
52.208-9	Contractor Use of Mandatory Sources of Supply or Services	OCT 2008
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	DEC 2010
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	JAN 2011
52.215-2	Audit and Records--Negotiation	OCT 2010
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data--Modifications	OCT 2010
52.215-13	Subcontractor Certified Cost or Pricing Data--Modifications	OCT 2010
52.215-14	Integrity of Unit Prices	OCT 2010
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions	JUL 2005
52.215-21	Requirements for Certified Cost or Pricing Data or Information Other Than Certified Cost or Pricing Data--Modifications	OCT 2010
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.216-7	Allowable Cost And Payment	DEC 2002
52.216-8	Fixed Fee	MAR 1997
52.217-2	Cancellation Under Multiyear Contracts	OCT 1997
52.219-6	Notice Of Total Small Business Set-Aside	JUN 2003
52.219-8	Utilization of Small Business Concerns	JAN 2011
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity for Veterans	SEP 2010
52.222-36	Affirmative Action For Workers With Disabilities	OCT 2010
52.222-37	Employment Reports on Veterans	SEP 2010
52.222-50	Combating Trafficking in Persons	FEB 2009
52.222-54	Employment Eligibility Verification	JAN 2009
52.223-14	Toxic Chemical Release Reporting	AUG 2003
52.223-18	Contractor Policy to Ban Text Messaging While Driving	SEP 2010
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.225-25	Prohibition on Engaging in Sanctioned Activities Relating to Iran--Certification.	SEP 2010

52.226-1	Utilization Of Indian Organizations And Indian-Owned Economic Enterprises	JUN 2000
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.228-7	Insurance--Liability To Third Persons	MAR 1996
52.229-3	Federal, State And Local Taxes	APR 2003
52.230-2	Cost Accounting Standards	OCT 2010
52.230-3	Disclosure And Consistency Of Cost Accounting Practices	OCT 2008
52.230-6	Administration of Cost Accounting Standards	JUN 2010
52.230-7	Proposal Disclosure--Cost Accounting Practice Change	APR 2005
52.232-2	Payments Under Fixed-Price Research And Development Contracts	APR 1984
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-22	Limitation Of Funds	APR 1984
52.232-23 Alt I	Assignment of Claims (Jan 1986) - Alternate I	APR 1984
52.232-25	Prompt Payment	OCT 2008
52.232-33	Payment by Electronic Funds Transfer--Central Contractor Registration	OCT 2003
52.233-1	Disputes	JUL 2002
52.233-3	Protest After Award	AUG 1996
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-3	Penalties for Unallowable Costs	MAY 2001
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.242-13	Bankruptcy	JUL 1995
52.244-2	Subcontracts	OCT 2010
52.244-5	Competition In Subcontracting	DEC 1996
52.245-1	Government Property	AUG 2010
52.245-9	Use And Charges	AUG 2010
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.201-7000	Contracting Officer's Representative	DEC 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	JAN 2009
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2008
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	JAN 2009
252.204-7000	Disclosure Of Information	DEC 1991
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7004 Alt A	Central Contractor Registration (52.204-7) Alternate A	SEP 2007
252.205-7000	Provision Of Information To Cooperative Agreement Holders	DEC 1991
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Terrorist Country	DEC 2006
252.211-7003	(INVALID EFF_DT) Item Identification and Valuation	DEC 1900
252.215-7000	Pricing Adjustments	DEC 1991
252.225-7002	Qualifying Country Sources As Subcontractors	APR 2003
252.225-7004	Report of Intended Performance Outside the United States and Canada--Submission after Award	OCT 2010
252.225-7006	Quarterly Reporting of Actual Contract Performance Outside the United States	OCT 2010
252.225-7012	Preference For Certain Domestic Commodities	JUN 2010

252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	MAR 2008
252.232-7010	Levies on Contract Payments	DEC 2006
252.235-7010	Acknowledgment of Support and Disclaimer	MAY 1995
252.235-7011	Final Scientific or Technical Report	NOV 2004
252.239-7001	Information Assurance Contractor Training and Certification	JAN 2008
252.242-7006	Accounting System Administration	MAY 2011
252.243-7001	Pricing Of Contract Modifications	DEC 1991
252.243-7002	Requests for Equitable Adjustment	MAR 1998
252.244-7000	Subcontracts for Commercial Items and Commercial Components (DoD Contracts)	NOV 2010
252.245-7001	Tagging, Labeling, and Marking of Government-Furnished Property	FEB 2011
252.245-7002	Reporting Loss of Government Property	FEB 2011
252.245-7003	Contractor Property Management System Administration	MAY 2011
252.247-7023	Transportation of Supplies by Sea	MAY 2002
USAMRAA 52.016-4006	CONTRACT CEILING (MAR 1999) (USAMRAA)	MAR 2007

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52.219-28 POST-AWARD SMALL BUSINESS PROGRAM REREPRESENTATION (APR 2009)

(a) Definitions. As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is ``not dominant in its field of operation'' when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/services/contractingopportunities/sizestandardstopics/.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it ( ) is, ( ) is not a small business concern under NAICS Code 541712- assigned to contract number TBD.

(Contractor to sign and date and insert authorized signer's name and title).

(End of clause)

52.232-20 LIMITATION OF COST (APR 1984)

(a) The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.

(b) The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that--

(1) The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or

(2) The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less

than had been previously estimated.

(c) As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.

(d) Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause--

(1) The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and

(2) The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.

(e) No notice, communication, or representation in any form other than that specified in subparagraph (d)(2) above, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.

(f) If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.

(g) Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.

(h) If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

(End of clause)

52.243-2 CHANGES--COST-REIMBURSEMENT (AUG 1987) - ALTERNATE V (APR 1984)

(a) The Contracting Officer may at any time, by written order, and without notice to the sureties, if any, make changes within the general scope of this contract in any one or more of the following:

(1) Drawings, designs, or specifications.

(2) Method of shipment or packing.

(3) Place of inspection, delivery, or acceptance.

(b) If any such change causes an increase or decrease in the estimated cost of, or the time required for, performance

of any part of the work under this contract, whether or not changed by the order, or otherwise affects any other terms and conditions of this contract, the Contracting Officer shall make an equitable adjustment in the (1) estimated cost, delivery or completion schedule, or both; (2) amount of any fixed fee; and (3) other affected terms and shall modify the contract accordingly.

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. However, if the Contracting Officer decides that the facts justify it, the Contracting Officer may receive and act upon a proposal submitted before final payment of the contract.

(d) Failure to agree to any adjustment shall be a dispute under the Disputes clause. However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

(e) Notwithstanding the terms and conditions of paragraphs (a) and (b) above, the estimated cost of this contract and, if this contract is incrementally funded, the funds allotted for the performance of this contract, shall not be increased or considered to be increased except by specific written modification of the contract indicating the new contract estimated cost and, if this contract is incrementally funded, the new amount allotted to the contract. Until this modification is made, the Contractor shall not be obligated to continue performance or incur costs beyond the point established in the Limitation of Cost or Limitation of Funds clause of this contract.

(End of clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

www.usamraa.army.mil

http://www.armet.gov/far/
http://farsite.hill.af.mil/vffara.htm

http://www.acq.osd.mil/dpap/dars/dfarspgi/current/index.html
http://farsite.hill.af.mil/VFDFARA.HTM

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any Defense Federal Acquisition Regulation Supplement (48 CFR 2) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

CONTRACTOR IDENTIFICATION (DEC 2005) (USAMRAA)

When contractor personnel perform the services required in this contract on a Government installation they are required to possess and wear an identification badge that displays his or her name and the name of the Company. The contractor shall ensure that contractor personnel identify themselves as contractors when attending meetings, answering Government telephones, providing any type of written correspondence, or working in situations where their actions could be construed as official Government acts.

While performing in a contractor capacity, contractor personnel shall refrain from using their retired or reserve component military rank or title in all written or verbal communications.

KEY PERSONNEL (MAR 1999) (USAMRAA)

a. The Contractor agrees to utilize the following Key Personnel on this contract:

Senior Coordinator
Study Coordinator
Volunteer Recruiter
Laboratory Manager
Specimen Manger

b. The above Key Personnel shall be utilized as necessary to fulfill the requirements of this contract.
c. The offerer must provide thorough and detailed documentation of the experience, abilities, and background for Key Personnel under this contract in the form of resumes or equivalent statements of qualifications. Such documentation should include but not be limited to: name, curriculum vitae, type and description of experience.
d. The contractor agrees that during the contract performance period substitution for Key Personnel shall not be permitted unless such substitution is necessitated by sudden illness, death, or termination of employment. In any of these events, the contractor shall promptly notify the Contracting Officer and provide the information required by paragraph (e) below.
e. All requests for substitutions must provide a detailed explanation of the circumstances necessitating the proposed substitution(s), a complete resume for the proposed substitute(s), and any other information requested by the Contracting Officer needed to approve or disapprove the proposed substitution(s). All proposed substitutes shall have qualifications that are equal to or higher than the qualifications of the person to be replaced. The Contracting Officer or his authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.
f. If any of the listed Key Personnel are subcontractor personnel, the contractor shall include the substance of this clause in any subcontract which he awards under this contract.

Section K - Representations, Certifications and Other Statements of Offerors

CLAUSES INCORPORATED BY REFERENCE

52.203-11	Certification And Disclosure Regarding Payments To Influence Certain Federal Transactions	SEP 2007
52.209-7	Information Regarding Responsibility Matters	JAN 2011
52.215-22	Limitations on Pass-Through Charges--Identification of Subcontract Effort	OCT 2009
52.222-38	Compliance With Veterans' Employment Reporting Requirements	SEP 2010
52.225-18	Place of Manufacture	SEP 2006
252.209-7001	Disclosure of Ownership or Control by the Government of a Terrorist Country	JAN 2009
252.225-7003	Report of Intended Performance Outside the United States and Canada--Submission with Offer	OCT 2010

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52.204-3 TAXPAYER IDENTIFICATION (OCT 1998)

(a) Definitions.

Common parent, as used in this provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

Taxpayer Identification Number (TIN), as used in this provision, means the number required by the Internal Revenue Service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may be either a Social Security Number or an Employer Identification Number.

(b) All offerors must submit the information required in paragraphs (d) through (f) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the IRS. If the resulting contract is subject to the payment reporting requirements described in Federal Acquisition Regulation (FAR) 4.904, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.

(c) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(d) Taxpayer Identification Number (TIN).

___ TIN:.----------

___ TIN has been applied for.

___ TIN is not required because:

___ Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

___ Offeror is an agency or instrumentality of a foreign government;

___ Offeror is an agency or instrumentality of the Federal Government.

(e) Type of organization.

___ Sole proprietorship;

___ Partnership;

___ Corporate entity (not tax-exempt);

___ Corporate entity (tax-exempt);

___ Government entity (Federal, State, or local);

___ Foreign government;

___ International organization per 26 CFR 1.6049-4;

___ Other----------

(f) Common parent.

___ Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.

___ Name and TIN of common parent:

Name----------

TIN----------

(End of provision)

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52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (JAN 2011)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is ---541712.

(2) The small business size standard is ----500 employees.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b)(1) If the clause at 52.204-7, Central Contractor Registration, is included in this solicitation, paragraph (d) of this provision applies.

(2) If the clause at 52.204-7 is not included in this solicitation, and the offeror is currently registered in CCR, and has completed the ORCA electronically, the offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

(__) Paragraph (d) applies.

(__) Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c)(1) The following representations or certifications in ORCA are applicable to this solicitation as indicated:

(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless--

(A) The acquisition is to be made under the simplified acquisition procedures in Part 13;

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.

(iii) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the clause at 52.204-7, Central Contractor Registration.

(iv) 52.204-5, Women-Owned Business (Other Than Small Business).This provision applies to solicitations that--

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.

(v) 52.209-5, Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(vi) 52.214-14, Place of Performance--Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.

(vii) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(viii) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(ix) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.

(x) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.

(xi) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.

(xii) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.

(xiii) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.

(xiv) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA-designated items.

(xv) 52.225-2, Buy American Act Certificate. This provision applies to solicitations containing the clause at 52.225-1.

(xvi) 52.225-4, Buy American Act--Free Trade Agreements—Israeli Trade Act Certificate. (Basic, Alternate I, and Alternate II) This provision applies to solicitations containing the clause at 52.225-3.

(A) If the acquisition value is less than $25,000, the basic provision applies.

(B) If the acquisition value is $25,000 or more but is less than $50,000, the provision with its Alternate I applies.

(C) If the acquisition value is $50,000 or more but is less than $67,826, the provision with its Alternate II applies.

(xvii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.

(xviii) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan--Certification. This provision applies to all solicitations.

(xix) 52.225-25, Prohibition on Engaging in Sanctioned Activities Relating to Iran--Certification. This provision applies to all solicitations.

(xx) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to--

(A) Solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions; and

(B) For DoD, NASA, and Coast Guard acquisitions, solicitations that contain the clause at 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns.

(2) The following certifications are applicable as indicated by the Contracting Officer:

(Contracting Officer check as appropriate.)

------(i) 52.219-22, Small Disadvantaged Business Status.

------(A) Basic.

------(B) Alternate I.

------(ii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.

------(iii) 52.222-48, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment Certification.

------(iv) 52.222-52 Exemption from Application of the Service Contract Act to Contracts for Certain Services--Certification.

------(v) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Alternate I only).

------(vi) 52.223-13, Certification of Toxic Chemical Release Reporting.

------(vii) 52.227-6, Royalty Information.

------ (A) Basic.

------ (B) Alternate I.

------(viii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at http://orca.bpn.gov. After reviewing the ORCA database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below (offeror to insert changes, identifyingchange by clause number, title, date). These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause	Title	Date	Change
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Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

(End of Provision)

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52.209-5 CERTIFICATION REGARDING RESPONSIBILITY MATTERS (APR 2010)

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that-

(i) The Offeror and/or any of its Principals-

(A) Are ( ) are not ( ) presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have ( ) have not ( ), within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) contract or subcontract; violation of Federal or State antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property (if offeror checks “have”, the offeror shall also see 52.209-7, if included in this solicitation); and

(C) Are ( ) are not ( ) presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision.; and

(D) Have [ballot], have not [ballot], within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds $3,000 for which the liability remains unsatisfied.

(1) Federal taxes are considered delinquent if both of the following criteria apply:

(i) The tax liability is finally determined. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(ii) The taxpayer is delinquent in making payment. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(2) Examples. (i) The taxpayer has received a statutory notice of deficiency, under I.R.C. Sec. 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(ii) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. Sec. 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(iii) The taxpayer has entered into an installment agreement pursuant to I.R.C. Sec. 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(iv) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(ii) The Offeror has ( ) has not ( ), within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) Principal, for the purposes of this certification, means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of provision)

52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (APR 2011) - ALTERNATE I (APR 2011)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is 541712.

(2) The small business size standard is 500 employees.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b) Representations. (1) The offeror represents as part of its offer that it ( ) is, ( ) is not a small business concern.

(2) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents, for general statistical purposes, that it ( ) is, ( ) is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it ( ) is, ( ) is not a women-owned small business concern.

(4) Women-owned small business (WOSB) concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (b)(3) of this provision.] The offeror represents as part of its offer that--

(i) It * is, * is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It * is, * is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(4)(i) of this provision is accurate in reference to the WOSB concern or concerns that are participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern or concerns that are participating in the joint venture: ----.] Each WOSB concern participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(5) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (b)(4) of this provision.] The offeror represents as part of its offer that--

(i) It * is, * is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It * is, * is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(5)(i) of this provision is accurate in reference to the EDWOSB concern or concerns that are participating in the joint venture. [The offeror shall enter the name or names of the EDWOSB concern or concerns that are participating in the joint venture: ----------.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(6) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it ( ) is, ( ) is not a veteran-owned small business concern.

(7) (Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (b)(6) of this provision.) The offeror represents as part of its offer that it ( ) is, ( ) is not a service-disabled veteran-owned small business concern.

(8) [Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The offeror represents, as part of its offer, that--

(i) It ( ) is, ( ) is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR part 126; and

(ii) It ( ) is, ( ) is not a joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(8)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. (The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture:_____.) Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(9) (Complete if offeror represented itself as disadvantaged in paragraph (b)(2) of this provision.) The offeror shall check the category in which its ownership falls:

____ Black American.

____ Hispanic American.

____ Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians).

____ Asian-Pacific American (persons with origins from Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Japan, China, Taiwan, Laos, Cambodia (Kampuchea), Vietnam, Korea, The Philippines, U.S. Trust Territory of the Pacific Islands (Republic of Palau), Republic of the Marshall Islands, Federated States of Micronesia, the

Commonwealth of the Northern Mariana Islands, Guam, Samoa, Macao, Hong Kong, Fiji, Tonga, Kiribati, Tuvalu, or Nauru).

____ Subcontinent Asian (Asian-Indian) American (persons with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, the Maldives Islands, or Nepal).

____ Individual/concern, other than one of the preceding.

(c) Definitions. As used in this provision--

Service-disabled veteran-owned small business concern--

(1) Means a small business concern--

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern," means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

Veteran-owned small business concern means a small business concern--

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

"Women-owned small business concern," means a small business concern --

(1) That is at least 51 percent owned by one or more women or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; or

(2) Whose management and daily business operations are controlled by one or more women.

(d) Notice.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small, HUBZone small, small disadvantaged, or women-owned small business concern in order to obtain a contract to be awarded under the preference programs established pursuant to section 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall--

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

(End of provision)

52.219-22 SMALL DISADVANTAGED BUSINESS STATUS (OCT 1999)

(a) General. This provision is used to assess an offeror's small disadvantaged business status for the purpose of obtaining a benefit on this solicitation. Status as a small business and status as a small disadvantaged business for general statistical purposes is covered by the provision at FAR 52.219-1, Small Business Program Representation.

(b) Representations.

(1) General. The offeror represents, as part of its offer, that it is a small business under the size standard applicable to this acquisition; and either--

___ (i) It has received certification by the Small Business Administration as a small disadvantaged business concern consistent with 13 CFR 124, Subpart B; and

(A) No material change in disadvantaged ownership and control has occurred since its certification;

(B) Where the concern is owned by one or more disadvantaged individuals, the net worth of each individual upon whom the certification is based does not exceed $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(C) It is identified, on the date of this representation, as a certified small disadvantaged business concern in the database maintained by the Small Business Administration(PRO0Net); or

___ (ii) It has submitted a completed application to the Small Business Administration or a Private Certifier to be certified as a small disadvantaged business concern in accordance with 13 CFR 124, Subpart B, and a decision on that application is pending, and that no material change in disadvantaged ownership and control has occurred since its application was submitted.

(2)___ For Joint Ventures. The offeror represents, as part of its offer, that it is a joint venture that complies with the requirements at 13 CFR 124.1002(f) and that the representation in paragraph (b)(1) of this provision is accurate for the small disadvantaged business concern that is participating in the joint venture. [The offeror shall enter the name of the small disadvantaged business concern that is participating in the joint venture: _____.]

(c) Penalties and Remedies. Anyone who misrepresents any aspects of the disadvantaged status of a concern for the purposes of securing a contract or subcontract shall:

(1) Be punished by imposition of a fine, imprisonment, or both;

(2) Be subject to administrative remedies, including suspension and debarment; and

(3) Be ineligible for participation in programs conducted under the authority of the Small Business Act.

(End of provision)

52.219-28 POST-AWARD SMALL BUSINESS PROGRAM REREPRESENTATION (APR 2009)

(a) Definitions. As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is ``not dominant in its field of operation'' when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/services/contractingopportunities/sizestandardstopics/.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it ( ) is, ( ) is not a small business concern under NAICS Code - assigned to contract number .

(Contractor to sign and date and insert authorized signer's name and title).

(End of clause)

52.222-22 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (FEB 1999)

The offeror represents that --

(a) ( ) It has, ( ) has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation;

(b) ( ) It has, ( ) has not, filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.

(End of provision)

52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APR 1984)

The offeror represents that

(a) [ ] it has developed and has on file, [ ] has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2), or

(b) [ ] has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(End of provision)

252.204-7007 ALTERNATE A, ANNUAL REPRESENTATIONS AND CERTIFICATIONS (MAY 2010)

As prescribed in 204.1202, substitute the following paragraph (d) for paragraph (d) of the provision at FAR 52.204-8:

(d) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at https://orca.bpn.gov/. After reviewing the ORCA

database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer, and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR/DFARS Clause #	Title	Date	Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

Section L - Instructions, Conditions and Notices to Bidders

SUBMISSION INSTRUCTIONS

L.1. Proposal General Information

This is a continuation of an existing requirement. The incumbent contractor is Clinical Research Management. The Government's total estimated cost is between $37,000,000.00 and $45,000,000.00 for the five year period.

This is a full and open competitive acquisition for the award of a non-personnel services Cost Plus Fixed Fee (CPFF) R&D contract. Award will be made to the best overall proposal, which is determined to be the most beneficial to the Government. This will be accomplished using the best value approach of subjectively evaluating non-priced factors, analyzing price, and possibly selecting for award other than the lowest-priced offer utilizing the trade-off process.

The Government intends to evaluate proposals and award a contract without discussions with Offerors, except clarifications. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary; the Contracting Offer will provide proposal revision instructions to the Offeror, as required. Therefore, the Offeror's initial proposal should contain the Offeror's best terms from a cost/price and technical standpoint. All proposals shall be subject to evaluation by a team of Government personnel who will evaluate only one proposal from each prime Offeror.

L.2. Proposal Submission

Offerors shall submit their proposal in accordance with the instructions outlined in Section L of the RFP. Failure to submit all documents concurrently and in accordance with the instructions outlined in Section L may render a proposal NON-RESPONSIVE.

Proposals shall be in 11-point Times New Roman font with margins no smaller than 1" on the top, bottom, and sides. The Government will not accept any other font.

1. SUBMISSION OF QUESTIONS: Offerors will be instructed to submit questions or comments regarding this solicitation no later than 08 July 2011 at 2:00 PM EST to the Contract Specialist and Contracting Officer. Questions submitted after the cut off time will not be accepted. The Government will answer all relevant and appropriate questions regarding this solicitation. Offerors shall **submit one set** of questions only; multiple emails will not be accepted. Questions not submitted electronically may not be answered. Answers to all relevant and appropriate questions will be issued via amendment to the solicitation.

   Contract Specialist

   The Contract Specialist (CS) is the point of contact for this acquisition. Any questions or concerns regarding this acquisition shall be submitted electronically via e-mail to kristen.trump@us.army.mil.

2. SUBMISSION OF PROPOSALS: Each section shall be separate and complete, so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the others.

Proposal Submission due no later than 29 July 2011 at 2: 00 PM EST.

VOLUME I – Executed RFP Documents - No limitation of pages

VOLUME II - Cost/Price Proposal – No limitation of pages

VOLUME III - Non-Priced Proposal

3. VOLUME CONTENTS

Volume I – Cover Letter and Executed RFP Documents

In Volume I, the Offeror shall complete and include all certifications required by the solicitation. This volume shall include the following:

a) Company cover letter

b) Standard Form 33 – Solicitation, Offeror, and Award, with blocks 12 – 18 completed by the Offeror.

c) Executed RFP documents (Section K Representations, Certifications and Other Statements of Offerors)

Volume II - Cost Proposal and Labor Category Pricing

RFP Section B — Costs: the offeror's proposed contract line item costs inserted in the appropriate space(s). Each Offeror should propose CPFF (Items 0001) in Section B.

Cost information shall be included in the Cost Proposal Volume II **only** and shall not be discussed or exhibited in any other part of the Offeror's proposal.

Offerors shall demonstrate they have the necessary financial capacity to perform this contract without assistance from any outside sources.

The Offeror shall provide full detail of the methodology and assumptions utilized as the basis for estimating costs.

Offerors shall address at a minimum all escalation factors applied to base costs, the basis for estimating labor utilization and the calculation of the hourly labor rate(s), the basis and rate calculations of all indirect cost factors to include historical and audited rates.

In addition, provide information regarding your accounting system and your ability to support Government cost-type contracts. Provide current (past 8 months) DCAA reports on adequacy, etc. Please note: prior to award, a preaward survey of the contractor's accounting system may be performed to determine that their accounting system is capable of adequately reporting costs on a cost-type

Government contract. Information regarding preaward surveys of prospective contractor's accounting systems can be found at www.dcaa.mil under publications, Information for Contractors Pamphlet.

Volume III - Non-Cost Proposal

This volume shall include five (5) sections, as follows:

Sub-section	Page Limitation
Tab a) Executive Summary/Abstract - - - - - - - - -	1 Page
Tab b) Technical/Scientific Approach - - - - - - - -	40 Pages
Tab c) Management Approach - - - - - - - - - - -	30 Pages
Tab d) Past Performance - - - - - - - - - - - - - - -	No Limit (3-5 References)
Tab e) Subcontracting Plan (if applicable) - - - - - -	No Limit

The Government will not consider pages submitted in excess of the stated page limitations. Tabs, table of content, resumes and letters of intent will not be counted against any page limits stated within the RFP.

4. ELECTRONIC FORMAT SUBMISSION

The Offeror shall provide:

Three (3) compact discs (CD's) containing its complete proposal, including all technical and cost data. The CDs shall be clearly labeled with: Offeror's name, solicitation number, and date.

Four (4) CD's containing only the Non-Cost Proposal as stated for Volume III.

Volume I and Volume III must be submitted in **BOTH** Microsoft Office format and Adobe Acrobat .pdf. Specifically, in the Cost Volume (Volume II) the fully burdened labor rates and cost buildup sections must be submitted in **BOTH** Microsoft EXCEL and Adobe Acrobat .pdf formats.

Failure to provide copies of the proposal in the acceptable formats may render a proposal non-responsive.

5. HARDCOPY SUBMISSION

The Offeror shall provide four (4) hardcopies of its complete proposal, including all technical and cost data submitted in the proposal. The volume of each proposal shall be contained in a separate three-ring binder with appropriate identification.

Proposals shall be submitted to the following address:

Director
US Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-W (Ms. Trump)
820 Chandler Street
Fort Detrick, MD 21702-5014

W81XWH-11-R-0014

All packages must be clearly marked with the Solicitation Number. No proposal received by FAX or email will be accepted.

6. OTHER INFORMATION

a. Offerors are referred to FAR 52.215-1, Instructions to Offerors – Competitive Acquisition, for general instructions on: submission, modification, revision and withdrawal of proposals; late proposals and revisions; offer expiration date; restrictions on disclosure and use of data; and contract award.

b. Evaluation of Proposals: The Government will evaluate proposals in accordance with the evaluation criteria set forth in RFP W81XWH-11-R-0014.

c. An offeror's proposal must stipulate that it is predicated upon all the terms and conditions of this RFP.

d. It is understood that the offeror's proposal will become part of the official contract file.

e. Proposal Contents: Proposals shall be clear, specific, complete, and concise, presenting complete effective methods and approaches for satisfying the RFP's requirements. Content shall be indexed (cross-indexed, as appropriate) and logically assembled and cost proposal submitted IAW FAR 15.408, Table 15-2 "Instructions for Submitting Cost/Price Proposals When Cost or Pricing Data are Required". The Government will evaluate **only one** proposal from each prime Offeror.

CLAUSES INCORPORATED BY REFERENCE

52.204-6	Data Universal Numbering System (DUNS) Number	APR 2008
52.214-34	Submission Of Offers In The English Language	APR 1991
52.214-35	Submission Of Offers In U.S. Currency	APR 1991
52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation	FEB 1999

CLAUSES INCORPORATED BY FULL TEXT

52.215-1 INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION (JAN 2004)

(a) Definitions. As used in this provision--

“Discussions” are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

“In writing or written” means any worded or numbered expression which can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

“Proposal modification” is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

“Proposal revision” is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

“Time”, if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) Submission, modification, revision, and withdrawal of proposals. (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, or revision, of proposals.

(i) Offerors are responsible for submitting proposals, and any modifications, or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii)(A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is “late” and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on

the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) Restriction on disclosure and use of data. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall--

(1) Mark the title page with the following legend: This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed--in whole or in part--for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of--or in connection with-- the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and

(2) Mark each sheet of data it wishes to restrict with the following legend: Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

(f) Contract award. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the
proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of provision)

52.215-20 REQUIREMENTS FOR COST OR PRICING DATA OR INFORMATION OTHER THAN CERTIFIED COST OR PRICING DATA (OCT 2010)

(a) Exceptions from certified cost or pricing data. (1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation

, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for certified cost or pricing data. If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.

As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of a Cost Plus Fixed Fee contract resulting from this solicitation.

(End of provision)

52.233-2 SERVICE OF PROTEST (SEP 2006)

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from

U.S. Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, MD 21702-5014

Attn: Wanda Harper
wanda.harper@amedd.army.mil

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of provision)

52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by

paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es):

www.usamraa.army.mil

http://www.armet.gov/far/
http://farsite.hill.af.mil/vffara.htm

http://www.acq.osd.mil/dpap/dars/dfarspgi/current/index.html
http://farsite.hill.af.mil/VFDFARA.HTM

(End of provision

52.252-5 AUTHORIZED DEVIATIONS IN PROVISIONS (APR 1984)

(a) The use in this solicitation of any Federal Acquisition Regulation (48 CFR Chapter 1) provision with an authorized deviation is indicated by the addition of"(DEVIATION)" after the date of the provision.

(b) The use in this solicitation of any Defense Federal Acquisition Regulation Supplement (48 CFR Chapter 2) provision with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of provision)

SAFETY PROGRAM PLAN (DEC 2006) (USAMRAA)

1. **Introduction**

This provision contains a description of the requirements, forms, approvals, and assurances relating to safety in the research environment. To ease the burden of submitting general institution safety program information with each proposal, the USAMRMC has developed a Facility Safety Plan program. If you have any questions concerning this provision please contact Ms. Cavelle Williams of the USAMRMC Safety Office at 301-619-6035 or email at mrmc-zc-sse.usamrmc@amedd.army.mil.

A Facility Safety Plan is a 2-10 page document that summarizes the institution's safety program. **Approval of the Facility Safety Plan is granted on an institution basis rather than on a proposal basis.** The Facility Safety Plan shall be institution-based, consist of six parts as outlined the Facility Safety Plan, paragraph 2 of this provision, and be prepared by the Facility Safety Director/Manager of the institution. Each institution is required to submit only one **Facility Safety Plan**. An institution with multiple research sites, subcontractor, or a consortium must submit a separate Facility Safety Plan for each research site. The Facility Safety Plan submission for each site will include signed assurances from both the Facility Safety Manager and Principal Investigator Assurance (paragraph 2 of this provision).

Facility Safety Plan approvals are granted for a 5-year period with annual updates required (See also clause entitled "**Facility Safety Plan Status Report" in Section "F"**). To determine if your organization has an approved Facility Safety Plan, check our website listing at: https://mrmc.detrick.army.mil/rodsohdfsplan.asp

a. If your organization's name **appears** on this Institutional Facility Safety Plan listing and approval of the Facility Safety Plan has not expired, then your institution's Facility Safety Plan need not be sent with the proposal submittal.

b. If either your organization's name **does not appear** on this Institutional Facility Safety Plan listing or the approval of your institution's Facility Safety Plan has expired, your Facility Safety Manager/Director must provide the U.S. Army Medical Research and Materiel Command's (USAMRMC's) Safety Office with a Facility Safety Plan and a signed assurance, as outlined below (part 2 of this provision).

2. **Facility Safety Plan (Institution-Based)**

The Facility Safety Director/Manager must provide information from the institutional perspective, as appropriate, for each of the six parts listed below. **This Facility Safety Plan should not reference the specific proposal.** A list of the first five components with a brief description of each is acceptable. **Do not send** institution safety manuals, although they may be referenced in your submission (a web site address is also acceptable). **Do not label** "Not Applicable" or "N/A". Each element shown below of the Facility Safety Plan should be addressed by providing a statement as it applies to your institution as a whole. **Example**: (see Radioactive Materials, part c) If your institution does not use Radioactive Materials and does not have a copy of the Nuclear Regulatory Commission (NRC), state-approved license, or the equivalent in cases of institutions outside the continental US then provide a statement to that effect.

a. Research Operations/Standard Operating Procedures (SOPs)
Provide a brief description of the safety procedures relating to the medical research operation of the facility. These should include (a) a description of any special skills, training, and SOPs that assure safe research operations (Bio-Safety Committee, Radiation Committee, HAZCOM, Blood-borne Pathogens, Chemical Hygiene Plan, etc.) and (b) a description of medical surveillance and support.

b. Facility Equipment and Description (Related to the Research Environment)
Provide (a) a description of the facility; (b) a description of personal protective equipment used within the facility; and a list of specialized safety equipment such as bio-safety cabinets, hoods, exhausts, and ventilation systems.

c. Radioactive Materials
Provide a current copy of the Nuclear Regulatory Commission or state-approved license.

d. Hazard Analysis (Related to the Research Environment)
Provide a description of each hazard identified, the hazard analysis performed based on maximum credible event and the plan to minimize or eliminate each hazard and control risk to laboratory personnel.

e. Biological Defense Research Program Requirements
(Only applicable to the Biological Defense Research Program funded awards)
For those institutions where Principal Investigators are supported by the USAMRMC and are conducting research with Bio-safety Levels 3 and 4 material, a Facility Safety Plan must be prepared in accordance with 32 Code of Federal Regulations (CFR) 626.18. See the following URL: http://www.access.gpo.gov/nara/cfr/waisidx_99/32cfr626_99.html for a copy of the 32 CFR 626.18, Biological Defense Safety Program.

f. Facility Safety Director/Manager Assurance
The Facility Safety Director/Manager must provide the following signed assurance:

Facility Safety Director/Manager Assurance

_____ I assure that this institution has an existing institutional safety and occupational health program that meets appropriate Federal, Sate, and local regulations as required by law, as well as the National Institute of Health Guidelines for Research Involving DNA Molecules, dated Jan 2001

_____ I assure that all hazards associated with the research laboratories have been identified, eliminated, and/or controlled in such a manner as to provide for a safe research laboratory environment.

_____ I accept full responsibility for submitting the annual **Facility Safety Plan Status Report** including significant changes in facility, safety equipment, and safety procedures by fax to 301-619-6627, by e-mail to mrmc zc-sse.usamrmc@amedd.army.mil, by mail to Commanding General, US Army Medical Research and Materiel Command, ATTN: MCMR-ZC-SSE, 504 Scott Street, Fort Detrick, MD 21702-5012.

_____ I assure that I have consulted with all current PI's holding USAMRMC awards concerning this institution's safety policies and procedures and will consult with all future PI's holding USAMRMC awards concerning this institution's safety policies and procedures.

Use of etiologic agents as defined in 32 CFR 626? _____ **YES** _____**NO**
"Etiologic agent = a viable microorganism, or its toxin which causes or may cause human disease, and includes those agents listed in 42 CFR 72.3 of the Dept of HHS regulations, AND any material of biological origin that poses a degree of hazard similar to those organisms.

_____
Name of Institution's Safety Director/Manager (print)

_____ _____
Signature Date

Mailing Address: _____
Street
_____
City State Zip Code
Phone Number: _____

Fax: _____

E-mail Address: _____

Web Site: _____

Principal Investigator Assurance

_____ I assure that I have involved the Facility Safety Director/Manager in the planning of this research proposal, discussed with him/her all aspects of the proposal that relate to occupational health and safety, and will help him/her prepare the annual Facility Safety Plan Status Report.

_____ I assure that I will comply with my institution's safety program and its requirements.

_____ I understand that I am directly responsible for all aspects of safety and occupational health specific to my research protocol.

_____ I assure that I will report to the Facility Safety Director/Manager any changes in the safety or occupational health practices due to changes in my originally planned research.

_____ I assure that hazards associated with my research have been identified, eliminated and/or controlled.

_____ I assure that all Safety Plan requirements are in compliance with 32 CFR 626 and 627, "Biological Defense Safety Program and Biological Defense Safety Program, Technical Safety Requirements" (*if applicable*).

_____
Name of Principal Investigator (print)

_____ _____
Signature Date

Mailing Address: _____
Street

_____
City State Zip Code

Phone Number: _____

Fax: _____

E-mail Address: _____

Section M - Evaluation Factors for Award

BASIS FOR AWARD

A. BASIS FOR AWARD

1. One award will be made based on the best overall value proposal that is determined to be the most beneficial to the Government, with appropriate consideration given to the following evaluation factors: Technical/Scientific Approach, Management Approach, Past Performance, and Cost. Non-Cost Evaluation factors are listed in descending order of importance. Technical/Scientific Approach and Management Approach are more important than Past Performance. The non-Cost factors combined are significantly more important than the Cost factor; however price may become the deciding factor if proposals are evaluated and determined to be literally equivalent on all Non-Cost factors. On the rare occasion that no relevant past performance exists within the offeror's organization or for whom information on past performance is unavailable, the Offeror will not be evaluated favorably or unfavorably on past performance but will be treated as a Neutral performance risk. If any of the above Non-Cost factors receives an individual rating of "unacceptable", the offeror's proposal will be deemed unacceptable. Only proposals receiving at least an overall rating of "acceptable" or higher will be considered for award. Proposals that are unrealistic in terms of "Non-Cost Factors will be deemed reflective of an inherent lack of technical competence or indicative of the offeror's failure to comprehend the complexity and risks of the contract requirements and may be grounds for rejection of the proposal. Offerors are cautioned that the award may not necessarily be made to the lowest-cost Offeror.

2. The Government reserves the right to:

a. Reject any or all proposals;
b. Award no contract at all depending on the quality of the proposal(s) submitted and the availability of funds;
c. Award to other than the lowest cost offer;
d. Waive informalities and minor irregularities in offers received; and
e. Award a contract without discussions

3. Each initial offer should contain the offeror's best terms from a Non-Cost Factors and cost standpoint.

B. FACTORS AND SUB-FACTORS TO BE EVALUATED

1. Technical/Scientific Approach.

2. Management Approach

3. Past Performance

4. Cost

C. EVALUATION APPROACH

The Government intends to evaluate proposals and award a contract without discussions with Offerors, except for clarifications. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary; the Contracting Officer will provide proposal revision instructions to the Offeror, as required. Therefore, initial proposal should contain the Offeror's best terms from a cost and technical standpoint. All proposals shall be subject to evaluation by a team of Government personnel who will evaluate only one proposal from each prime Offeror.

The solicitation will be for a 5-year multi-year service period where potential bidders will propose on the performance based statement of work. To be considered for award of the contract, each offeror must be determined fair and reasonable.

Factor 1 Technical/Scientific Approach:

a. Approach: The Offeror shall define a technical approach that conveys its capabilities, technical expertise, tools, techniques, identify technical uncertainties and make specific proposals for resolution, strategies, and methodologies to be applied to the functional areas described in Section C. The proposal must indicate a thorough understanding of the Performance Based Work Statement (PBWS) (Section C) and provide a comprehensive approach as to how tasks will be accomplished. The Offeror must clearly state and justify any exception to or variation from the requirements. The offeror must provide a Certificate of Competency (COC) which is a certificate issued by the Small Business Administration (SBA) stating that the holder is responsible for the purpose of receiving and performing a a specific Government contract.

b. Understanding of Requirements: The proposal will be evaluated to determine if the Offeror has a clear and complete understanding of the PBWS and if the Offeror provides a realistic and logical technical approach and plan of performance for the requirement. The proposal will be evaluated to determine if appropriate and qualified personnel are proposed for the requirement. The proposed man-hours will be evaluated for reasonableness and to determine if the labor categories and description of other related direct costs (travel, lodging, per diem, auto rental, etc.) are sufficiently substantiated. The estimates will reflect an understanding of the effort required to successfully complete the effort reflected.

c. Feasibility of Approach: The proposal will be evaluated based upon the extent to which successful performance is contingent upon proven methods and techniques, and the extent to which the offeror's methods and approach to the Contract are expected to result in successful completion of the proposed technical requirements within the required schedule.

Factor 2. Management Approach:

This section shall identify the Offeror's understanding, approach, methods, ability to satisfy the requirements of the solicitation and shall be logically organized. The Offeror must present a comprehensive plan that supports the requirements of this solicitation. Offerors must clearly delineate the line of authority associated with the proposed organization and its ability to plan, organize, and use resources in a coordinated and timely manner in order to achieve technical requirements and control costs.

a. Overall Approach: The Government will evaluate the degree to which the Offeror's methodologies, processes and capabilities reflect an ability to efficiently and effectively manage the contract. This section shall include the evaluation of requirements support, resource management and human resources development to the degree in which the Offeror demonstrates the ability to control, coordinate, and direct performance requirements, organize and manage resources that will achieve technical requirements. The ability to acquire and retain professional and technical staff, potential sources that are qualified based on present and past performances of similar work, professional stature and reputation and relative position in a particular field of endeavor and support development structure.

b. Subcontract Approach and Expertise: The Offeror shall be evaluated for demonstrated expertise and capability to manage/administer subcontractors, including procedures used and successes in subcontracting efforts during the past three years. Any subcontracting arrangements contemplated by the Offeror must be presented to the Government in detail in a Subcontracting Plan. The Subcontracting Plan shall be included as a part of the proposal. The plan shall disclose the subcontractor's tasks and be presented in enough detail to allow the Government to determine how much subcontracting the Offeror contemplates. Also, goals in terms of what percentages are forecast on subcontracting with different socioeconomic small businesses should be provided.

Factor 3. Past Performance

Offerors shall provide documentation showing the degree of relevancy and success in past performance efforts for the past 5 years of similar technical scope, size, complexity, and similar subject matter in accordance with the solicitation. The offeror's record of past performance information will be used to assess the relative risk associated with the proposal and the probability of successful accomplishment of the required effort.

a.. The Offeror will be evaluated based on the narrative description of the number and type of contract work performed similar in technical scope and complexity to the requirements of this solicitation. Offeror shall provide a brief description of contract work and comparability to the proposed effort. It is not sufficient to state that it is similar in magnitude and scope, a rationale must be provided to demonstrate that it is comparable. Projects completed or in progress described in the narrative will be evaluated for scope and degree of support to DOD, other federal agencies, or other comparable international organizations.

b. Offerors shall describe problems encountered in the performance of similar services and describe how the problems was/were resolved.

c. Each Offeror will be required to forward a copy of the Past Performance Questionnaire to references of their choice for completion. The questionnaire shall then be returned directly to the Contract Specialist by the selected references prior to the closing date and time of the solicitation. This information will be used to assess the relevancy of performance risk involved in accepting each offeror's proposal.

d. Offerors are advised that in evaluating past performance, the Government may use data provided by the Offeror, from the Past Performance Questionnaire, and data obtained from other sources. Offerors are reminded that while the Government may elect to consider data obtained from other sources, the

burden of proving low performance risk rests with the Offerors.

e. On the rare occasion that no relevant past performance exists within the offeror's organization or for whom information on past performance is unavailable, the Offeror will not be evaluated favorably or unfavorably on past performance but will be treated as a neutral performance risk.

Factor 4. Cost / Price –

Cost realism will be used to evaluate the cost proposal to ensure that the proposed prices reflect a clear understanding of the work and skills required for contract performance. The government will evaluate the cost realism of the offeror's proposed costs in relation to the offeror's specific technical approach.

The Government may utilize the Defense Contract Audit Agency (DCAA) and the Defense Contract Management Agency (DCMA) as appropriate to assist in the evaluation of the proposed cost, the Offeror's accounting system, and financial capability. The Government will utilize weighted guidelines to analyze the Offeror's profit or fee to determine if it is reasonable in light of the associated risk.

Offeror should take note of FAR Clauses 52.230-2, 52.230-3 and 52.230-6 located in Section I of the Solicitation. The Offeror shall provide copies of current DCAA audit reports, forward pricing rate recommenations or rate agreements, and ACO determination letters that are applicable and relevant to the proposal.

The Offerors will be placed on notice that any proposals that are unrealistic in terms of Non-Cost factors or unrealistically low in cost(s) and/or price will be deemed reflective of an inherent lack of technical competence or indicative of failure to comprehend the complexity and risk of contract requirements, and may be grounds for rejection of the proposal.

Although cost will not be a consideration for the SSEB to evaluate, the cost of each proposal will be evaluated by the Contract Specialist and the Contracting Officer and evaluations will be shared with the SSEB after evaluations are completed.

Cost will not receive an adjectival rating. However, if proposal evaluations result in findings that Offerors are essentially rated equally in non-cost factors, cost could become a determining factor based upon an assessment of cost realism and fee/profit.